decrease in missed lesions? Do you have any measurable evidence that quality in this area has been improved with your mandatory program in effect? Thank you.

MR. FLATER: No, ma'am. We do not. We do not track that.

CHAIR HENDRICKS: Yes. Dr. Ferguson.

MEMBER FERGUSON: My question after listening to all the discussion earlier about mandating accreditation which I think would certainly improve in a lot of areas. The only area that I hesitate in is in access for rural areas. I think you started off saying about you had many small hospitals and Iowa is a rural state. Do you have problems with access? How far do people have to go to be able to get a stereotactic biopsy?

MR. FLATER: I can't tell you on the stereotactic side, but I can tell you on the normal side. We may be one of those aberrations in the whole process. We have grown in size ever since the program started in the 1990s. We started out with 141 mammography facilities. As I said, we are now

at 156.

For whatever reason, our farming communities want their mammography facilities so that they are very accessible and they're more than willing to pay for that. We have two of the digital units in the State of Iowa. One of those is one in a very small town of Storm Lake, Iowa. It was given by a farmer who gave the hospital the farm and said, "You must make a women's center" which was paid for with cash including a stereotactic unit.

So we are having no problem with accessibility. We haven't lost any of the stereotactic units as far as them quitting or anything like that. We haven't had that kind of a problem.

MEMBER FERGUSON: And you do have them in relatively small communities.

MR. FLATER: They're spread out. Most of them are in the 200 bed and greater hospitals but they're spread out throughout the state. We have the major centers of course spread clear out through the state. They do have to go a little further but

not that far. Most of them will take that when they get to that far part. The surgery when they get the confirmed cancer, they will do whatever they need to do in order to get that kind of service.

MEMBER FERGUSON: Do you, and I'll be short, have any type of program for women who don't have the means to travel for care, for gas, for transportation? Do you have any programs like that?

MR. FLATER: We have the breast cancer detection centers set up within the state health department and they will pay for individuals that need to have the different kinds of exams. I cannot tell you for sure what they will do for the stereotactic. I know for the diagnostic that they pay for them on a routine basis.

MEMBER FERGUSON: Thank you.

CHAIR HENDRICKS: Carolyn Hendricks, Panel Chair. Just a question about the pattern of violations that you've seen during your inspections of the stereotactic units. For example, from the data that we see from MQSA is there a high proportion of facilities with no violations or where

these violations scattered across facilities? Other than the three that you indicated might be related to fraudulent behavior of one employee, how were the remainder of the violations scattered across the facilities?

MR. FLATER: We don't see them. There are a few here and there like we missed some of the surveys and that kind of thing, but they're sort of sporadic and sometimes they are ones that it's just an "Oops" they didn't make it within the 14 months. It may be because it was 15 months. Many of our physicists are much like Melissa or they travel so getting them coordinated so they happen at the exact time. They may be at 15 months instead of 14 months and that kind of thing.

So we're not seeing them lumped together or anything like that and we're not seeing repeats. Repeats we watch very closely because in our system of regulation if it repeats, if you repeat one time, you are eligible for civil penalty and our civil penalty is $1,000 per violation, I'm sorry, $1,000 per violation per day for every day of violation.

So if you find it and it runs for a routine period of time, it can get expensive real quick. So they are very much aware of that and they try very hard to not have it. We don't have anybody who are "bad actors" if you will. We've gotten rid of most of those through the regular MQSA program.

CHAIR HENDRICKS: Thank you very much. When you added stereotactic to your mammography inspection procedures, did you find or did the facilities or the physicians, the technicians, the physicists feel that the requirements increased their burden?

MR. FLATER: I don't believe it did for the same reasons that Penny gave. We had the MQSA in. They were used to that. My folks are in there so often that it's just a routine type thing. We call ahead of time. We make scheduled visits. We've even gone to a point that if they're very busy on the day we need to come in that we'll do it late afternoon or some time when the unit isn't in use. So we've accommodated the facilities that way. I don't think that there's been a problem with patient

flow. There may have been a bit of a problem with people having to spend a little overtime if we come in at night and that kind of thing.

CHAIR HENDRICKS: Thank you very much. Other questions or comments from the panel or from the audience?

CHAIR HENDRICKS: I do have a follow-up question related to how you handle specifically the physician personnel. If you had, for example, surgeons who wanted to participate who did not meet your criteria as outlined in the guidelines, how do you manage that in your facilities?

MR. FLATER: They aren't allowed to do it. It's plain and simple. It's the rule and they have to meet the rule. The rule went through a complete hearing process. We've worked with the surgeons group. We've worked with the radiologists and if you can't do it, you can't do it because it relates back to the care of the patient and it needs to be a qualified individual who is properly trained and that's the general philosophy that we follow.

CHAIR HENDRICKS: Other questions or

comments, Panel members? The audience? Thank you. Very interesting presentation.

MR. FLATER: Thank you.

CHAIR HENDRICKS: Next we welcome Dr. Barr back to the microphone to continue her discussion for the panel and for the audience reviewing the Institute of Medicine Recommendations Regarding Interventional Mammography. Dr. Barr.

DR. BARR: Thank you very much. Again since this is probably my last opportunity to speak with you, I wanted to thank you once again all for being here and for giving us your expertise and thank you to the members of the audience who have provided their expertise, thoughts and opinions.

First, I would like to go back to yesterday because I thought that there was a slide in here about this IOM recommendation and there wasn't. So I neglected to cover this yesterday and a couple of people have spoken about it today. One of the IOM recommendations was to change MQSA to Breast Imaging Quality Standards Act to include all breast imaging procedures apparently. I'd like to

point out that when we were discussing things like ultrasound and MRI, etc. that since that's not defined as x-ray of the breast, this particular thing instead of a regulation would require statutory change to include other non x-ray imaging modalities under a statutory act like this. I just wanted to make sure that everybody was aware of that.

What I'm going to do is quickly run through the slides I have on the IOM recommendations related to stereotactic breast biopsy and then after lunch, we can have a discussion related to this.

One of the IOM's recommendations was to remove the exemption for stereotactic breast biopsy procedures and develop regulations. Section 900.2(aa) states that mammography means radiography of the breast but the purposes of this part does not include radiography of the breast performed during invasive interventions for localization or biopsy procedures, but they would like to delete those words, or biopsy procedures and radiography of the breast performed with an investigational

mammographic device as part of the scientific study with FDA's investigational device exemption. This is also not part of this.

So the rational to remove the part that would exclude biopsies, stereotactic breast biopsy, this is IOM's rational. While it uses mammographic x-ray imaging, FDA indicated its intent to regulate interventional and that was in the preamble to the proposed final regulations in 1996. The profession now has more experience with stereotactic procedures and I would assume in there is the fact that there is an accreditation program for stereotactic imaging.

These are some comments in the report by IOM on interventional mammography regulations. It talks about the ACR and American College of Surgeon joint qualification set for physicians performing stereotactic breast biopsy which includes requirements for CME and continuing experience. These standards became the basis for ACR's and American College of Surgeons' voluntary accreditation program.

It says, "However in testimony to the Senate Committee on Health, Education, Labor and Pensions on the reauthorization of MQSA, the American Cancer Society noted of the 4,000 to 5,000 interventional mammography machines," I note the up to 2,000 increase in stereotactic units predicted than we've heard from other sources. Fewer than 500 are accredited through the ACR program. Only 11 are accredited by the American College of Surgeons' program. In similar testimony, speakers on behalf of the Komen Breast Foundation and the Society of Breast Imaging advocated removing the exemption on interventional mammography procedures.

The committee urges FDA to remove the exemption of all interventional mammography from MQSA. I see here that they're including all stereotactic biopsy procedures and equipment used for interventional procedures such as needle localization. But I'm not sure that the wording to make that happen was part of the recommendation. But anyway, here it says that they apparently intend their recommendation to include needle localization

should be regulated. There is no accreditation process for needle localization in place at the moment.

The committee believes mandatory accreditation of interventional equipment, not the interventional procedures themselves is sufficient. That stands on its own, I guess. In addition, FDA inspectors should be trained to perform onsite inspections of stereotactic breast biopsy procedures and interventional equipment as a paper review and review of films obtained by the site would be insufficient for insuring quality.

Just some thoughts as we prepare to discuss this issue this afternoon. Since I came into FDA six years ago, I have repeatedly asked the question and some of you have heard it because you've been on this committee before that we're a public health agency and where is the public health risk to patient if we're not regulating these biopsy procedures. So far, I have heard reasoning that we should regulate them because we said that we were going to. I've heard reasoning that we should

because these procedures involve x-ray, imaging of the breast. I've heard, and not to diminish them in any way, anecdotal reports of patients who have had their lesion missed on core biopsy which of course if we go through we can hear about any medical procedure.

What I have not heard is the evidence that we had back when MQSA came into effect that there's a risk to the general public health, not to individual patients, but to the public in general where we had a nation wide survey that showed us the poor image quality of mammography and the problems with dose and I have not to-date heard evidence that in places where there are mandatory programs that there is factual evidence that we can point to that regulation has improved quality in this area. I think in MQSA we have the 25 percent reduction in breast mortality and although we can't specifically say that's MQSA we know that in large part in addition to improved treatment that MQSA has to be a part of that mortality decline.

We searched our own database here from

our Office of Surveillance and Biometrics who gets reports in on any medical device that's being used that has some sort of problem related to it. We had them look back in the last two and a half years. They found six reports related to interventional procedures.

It was often difficult to sort out what the person reporting was actually trying to report. But as best as we could determine of those six reports a number of them were related to inadvertently pulling out a needle during procedure. I can only assume that probably was related to needle localization. I can't see where that would happen too often with core biopsy. At one point a couple years ago, there were reports of one stereotactic needle that the tip could shear off. So that's information that we have that we can add into this discussion here.

MEMBER MARTIN: Dr. Melissa Martin. I guess the only thing I would reiterate is the data that Penny Butler showed from the voluntary accreditation program that approximately one-third

of these facilities who we would assume are the ones that think they are doing good work are not meeting the initial or the repeat rate for accreditation. I think that is hard data that we have to work with.

DR. BARR: And that same thing did happen in mammography when we first started too. What I was asking Ms. Butler is if we have any evidence that those failures relate to a lesion not being captured. Since the facility is submitting its best work, it's certainly hard for me to believe that they would submit films on procedures where they didn't obtain the diagnosis.

So do we have any correlation that these failures relate to a nondiagnostic core biopsy? Certainly there are accreditation failures and we can say whatever we want. It just like Ms. Butler said. We don't have it for mammography. Does failing mammography accreditation mean that they're nondiagnostic mammograms?

I've seen a number of the mammograms in our review process that fail accreditation and there are things that could be better about the mammogram.

But in most circumstances, it doesn't mean the mammogram wasn't diagnostic. In these circumstances, do these accreditation failures mean that if we're saying one-third of these facilities are missing? They're not diagnosing, not capturing, the lesion on core biopsy then I think that's a serious problem. I'm not sure that accreditation failure means that.

CHAIR HENDRICKS: Yes. Dr. Williams.

MEMBER WILLIAMS: This is Mark Williams. My guess is that the data that you're looking for are probably a little bit difficult to obtain since what we need to get would be some tracking somehow of what ultimately turned out to be false negatives on missed biopsies. One example that strikes me is that is that of excisional biopsies in which wire localization was used. We get reports that wire localization is done correctly and that it's accurate and I think in most cases it is.

However we talk to the surgeons and the surgeons say, "The wire sometimes misses the lesion by up to a centimeter or more" and the reexcision

rate for positive margins is about 50 percent. Now not all of that can be attributed certainly to poor localization. However it just shows that if you dig into the process as to what all the things that could contribute to those that those miss, I think it's very feasible that's part of the localization or the imaging process that could be playing a role. It's just very hard to segment that out from the other things.

DR. BARR: Yes. And I certainly agree with you and I certainly agree with your statement about wire localization. I think it is a fairly inaccurate way to go about making the diagnosis of breast cancer. Yet interestingly enough, where we probably have more evidence that repeat excision rate indicates that wire localization is not always accurate we don't have an accreditation program that deals with people's ability to do wire localization.

MEMBER WILLIAMS: Right.

CHAIR HENDRICKS: Input from other panel members? Yes.

MEMBER MOUNT: Carol Mount. In my

observation of some of the rural areas where we have both radiologist and surgeons using a stereotactic table that is not accredited, I get frequent calls from the radiologists at those facilities saying, "What can we do about this because the surgeon is in there without a technologist trying to position this patient?" Finally I said, "Why don't you count the number of exposures that they have taken, the number of times they've tried to position that patient and not been able to find the area that they're looking for? Maybe then you could work with the physicist to actually get the dose that patient received during that attempt."

They started doing that. The surgeon is still doing stereotactic biopsies and they are going to get accredited and thus my earlier question as to what do you do if the radiology department is accredited and the surgeon is not, so two facilities that I know of in our immediate area that that very thing is happening. I think if this does move forward there has to be very specific dose and positioning training offered to those physicians if

they're not going to have a technologist in the room helping them.

CHAIR HENDRICKS: Thank you. That's a useful comment and it's exactly the kind of information as a public health official that I would like to see which I'm not seeing at least on a basis other than anecdotal exactly the kinds of things that you're talking about.

MEMBER MOUNT: They don't know what to do with it or who to go to.

CHAIR HENDRICKS: Thank you. Other comments from the panel? I do have a follow-up question for you, Dr. Barr, related to how we can today as part of this meeting use the preliminary data from the ACR voluntary accreditation process. Because as I heard that data for the first time, I do think that it speaks to some significant technical problems and issues related to the skill of the surgeons and radiologists performing the procedure at this point in time.

Because if you look at the information that was presented, the bar was set relatively low

as I understand it. In the two tracks, the requirement is to perform perhaps the 12 procedures in a year and then submit one set of films really on the calcifications which is really the role of stereotactic biopsy procedure. So the facilities, the voluntary participants, have submitted just one case out of the minimum of 12 and we have acknowledge that the failure rate does speak to a significant issue related to skill.

Now it's true if we don't have the outcome, we will never be able to produce survival data, I think, in this area, but it does speak to a significant problem with the technical and the skill of the physicians doing the procedure in my mind.

DR. BARR: I think what it speaks to if it's my understanding and certainly Ms. Butler can correct me if I'm wrong is that we have reviewers saying that we don't think that your needle is placed properly to obtain a diagnosis or perhaps again it would seem to me kind of insane to submit specimen radiographs of a lesion with calcifications and not include them in the specimen. Certainly,

that's a technical issue.

I don't think we need outcome data. It would be very easy to have the radiology report and the pathology report submitted along with that so we could see if these needle placement failures result in the lesion being missed or are we failing people on something that doesn't relate to the outcome?

I think the way we can use the information is in a number of different ways. We could do what the IOM says and we could remove the exemption for stereotactic. We could adopt the existing accreditation programs and we could develop an certification procedure and then an inspection procedure. We could say that everybody has to be accredited but have no certification or inspection procedure. There's a number of different ways we could go about this.

I don't know what we would do actually in the case of wire localizations since there is no accreditation program. And certainly, I'm not ignoring the failure rate just as we didn't ignore it in mammography. I'm just not sure what it means

and I'm not sure what other evidence like we had with MQSA that we are putting the public at risk by continuing to have the exemption for this.

CHAIR HENDRICKS: Thank you. Dr. Dowlatshahi. Please reintroduce yourself for the record.

DR. DOWLATSHAHI: Dr. Dowlat, Chicago. I have a question about the actual number of the stereotactic devices in the country. The Institute of Medicine quotes to 4,000 to 5,000 machines. I think someone mentioned as far as I called up the manufacturers is it's about 2,000, maybe 2,500. Which one is correct?

DR. BARR: I don't know and I brought that point up. I don't know. It appears the Institute of Medicine is quoting the American Cancer Society with their estimate. Again, I'm not sure we have an accurate answer to that. It would seem to me that manufacturers are the people that could give us the most accurate information about how many units were sold.

EXEC. SECRETARY FINDER: It's Dr.

Finder. I just want to clarify one thing and ACR and ACS can correct me if I'm wrong. The review of the calcifications and mass, it's one per facility, not per physician and a facility. Is that correct?

MS. BUTLER: Penny Butler, ACR. It's one per unit.

EXEC. SECRETARY FINDER: Per unit. Sorry.

DR. BARR: So I think Dr. Finder at least obliquely gets to a point which I brought up earlier. I think experience has told us it's not equipment necessarily that's the problem, but the use of that equipment. As you heard Lt. Commander Boyd say our whole focus around health, our strategic planning is to focus on high risk procedures and those where use is a problem we find that users of devices are more where the problem lies.

Here even in this accreditation program it doesn't appear that we address each user of that but again the equipment. Obliquely the user or someone had to place the needle for the films we're

looking at.

MEMBER MARTIN: Melissa Martin. I am a consulting physicist and like I said, we cover all of these units because it's a state requirement. But there is really no teeth to any requirement as to what the image quality has to be.

I would go back to, I think, Dr. Williams made the point earlier or Penny Butler may have made the point earlier, when MQSA first became effective we did see a number of units that were removed from service because they are equipment related problems. It's a generation problem. They do wear out and a lot of exactly what I'm finding. It's the older equipment that is getting worn out. It doesn't meet state-of-the-art, what we would have in a modern day if you went out and bought a new unit. But until there's some requirement that says the unit you bought ten years ago is not adequate now, they're going to continue to use it.

DR. BARR: Now we do have, I would like to point out, equipment requirements in MQSA, at least, that equipment has to meet.

MEMBER MONTICCIOLO: This comment actually just relates to the needle localization issue and I don't know about the other radiologists or surgeons here but I wasn't really prepared to address that as a regulatory issue. While localization requires a tremendous amount of cooperation between the radiologist and surgeon, I don't personally having practiced in several different types of practices in different areas of the country, I've never seen wire localization be a significant issue.

The reason is if you're not wire localizing well, the surgeon is going to know it in a second and they're going to come down. Having been a division chief at several places, now I'm going to be the first one to hear about if any of my staff can't wire loc adequately. It's a very basic procedure. It's fairly straightforward. It can be very difficult if a lesion is in a difficult spot in a patient's breast. But we put the wire through the lesion and we have to document it because the films come out with the wire and the breast there on the

same film. So it's very hard for us to wiggle out of that. Then a specimen comes back.

Now we do have a problem with some of the older surgeons not believing they need a specimen x-ray to confirm the lesion has been removed. I don't know if regulation would deal with that or not. But certainly the pathologist's report is there. There's either pathology in the specimen that corresponds or it doesn't. I'm not sure if that type of program is needed. It would be onerous I think to develop.

DR. BARR: I know in my practice once we go stereotactic unit even if the patient was for open biopsy, we use the stereotactic unit to localize the lesion rather than free-hand localization. Do you find that in your practice?

MEMBER MONTICCIOLO: No, we don't use the stereotactic table for that. It's useful for lesions that are only seen in one projection because on the stereotactic table as you know, you can do slight off-angle views and get an idea of where the lesion lies.

DR. BARR: Yes.

MEMBER MONTICCIOLO: But that doesn't happen to us very much nowadays with the current equipment. I have done several localizations with stereotactic and usually the issue is that the patient is in a lot of compression and so I find I have to compensate for that and then drop the wire deeper than I would normally for a regular loc. But we generally just use the mammographic equipment and our mammographic equipment is all accredited and passed by MQSA. So I don't see the issues that we have with stereo with localization.

DR. BARR: Since the IOM is apparently including wire localization in their recommendation, could I get some further sense of the committee in that particular area where there is an accreditation program that exists? Is that something we should look to include in federal regulation leaving stereo aside for the moment?

MEMBER MONTICCIOLO: I think that the equipment should be accredited because you ought to be able to form a diagnostic image and I'm not too

fond of the idea of somebody saying that old machine we have over there we'll just use that wire locs. I think we're wire localizing smaller and smaller lesions and so the equipment has to be accredited in the equivalent of the others.

We use a mammogram unit that's used for regular mammogram to do our localizations and I think the equipment regulation would be important. Developing an entire program to see if people doing the wire locs are able to do them, it requires so much cooperation with the surgeon that even if I wire loc something perfectly they can miss a lesion just by yanking on the wire. That wire will come right out.

I have a very good relationship with my surgeon. She's fantastic but she occasionally will miss it and she'll say, "I let a resident and he grabbed on the wire and away it went." Those things happen. It's not something intended but then we have to go back and help each other do what's right for the patient. So that would be pretty hard to put into a regulatory statute.

DR. BARR: So you would be in favor of lifting the fact that there can now be equipment if it's only used for wire localization, it doesn't have to meet MQSA requirements. You would say that it does.

MEMBER MONTICCIOLO: I think it should. Yes, I would.

DR. DOWLATSHAHI: Dr. Dowlat from Chicago. I think the published report on the wire localization cancer being missed is under two percent and I got the impression from you that you're talking about a much higher figure. I agree with Dr. Monticciolo too that the wire localization is an issue between radiologists and the surgeons. There are times that you do get displacement of the wire and while I double localize, I put wire as well as dyes. So if the wire comes out, the dye is still there. But there are times that you have missed it and the specimen doesn't show it and you have problems, but you tell the patient and you go after it in a couple weeks or thereafter. You don't let the suspicious lesion go by.

DR. BARR: I agree with you. I was only commenting on Dr. Williams' comment that we have reexcision data related to wire localizations. I'm not sure that we have the data like you can tell me how many lesions are generally missed, being excised with wire localization. But can you tell me how many lesions are missed or what the repeat rate is for stereotactic or how many lesions are missed on stereotactic that then go to wire loc?

DR. DOWLATSHAHI: I think the wire localization with the stereotactic is a little bit more dicey the same as it was pointed out a minute ago because after decompression, the wire may move. In my experience, I put more than one for sure. I put usually two. Sometimes if the lesion is a little bit spread out, maybe I even put three wires just for security and add the methylene blue dye to it.

But I think the localization not being perfect, by that I mean with one centimeter, hooking within one centimeter of the lesion, it occurs more with the stereotactic localization than with the

orthogonal technique.

DR. BARR: Right. But my point is you were able to come up to this podium and right away tell me that the miss rate on excisional biopsy with wire localization is under two percent. Do we have the same data for stereo?

DR. DOWLATSHAHI: For stereotactic, no, I think the number I gave you is probably the orthogonal technique and not stereotactic because I can't think of the papers. But it is at least close to eight to ten years old.

DR. BARR: Thank you.

DR. DOWLATSHAHI: It was pre stereo I think.

DR. BARR: Thank you very much. Did you want to go first?

MEMBER WILLIAMS: Yes, if I could. I have three comments that I think we ought to bear in mind. One is that places like, I agree with Debbie 100 percent that it's a cooperative venture, the wire loc, between the radiologist and the surgeon. I think that in places that work together well and

have very well trained personnel, it can come off very well. But that may leave out a vast portion of our country where people are not necessarily working as tightly together and not necessarily as well trained. So that's one thing.

The second thing is that when I speak to our surgeons at the University of Virginia, we have our breast care center is among the top, what I find out is that really what's going on and this is not to take anything away from the radiologist, they're very good, but the surgeons are very good at being able to take the two views with the wire in there and triangulate and correct if they can see the lesion in the image and figure out where the wire was really supposed to go. So part of this is we have to ask ourselves to want to really have to force the surgeons to have to do that.

The third comment I would make is that as we detect cancers earlier and earlier and we get a larger fraction of non-palpable lesions, I think even these compensations are going to become tougher and tougher, that is, for the surgeon to make on the

fly because it may not be that apparent when they get in there. So I would put that up as a cautionary note before we completely discard the idea of looking into wire loc.

DR. BARR: Thank you.

MEMBER MONTICCIOLO: Debbie Monticciolo. I would just say that I think there is data on the miss rate on stereos. There have been many papers put out looking at miss rates and they have been found to be equivalent to the surgical miss rate which is often quoted at less than two percent. So there is that data.

The second thing I would add and I think Penny point this out is that we're not required when we're accredited for stereotactic to give data on our misses and complications but it's requested. You feel pretty awkward submitting that document without that information and we do it. Obviously it's a voluntary program, but we always look at it and we have data on all of the things that we felt were discordant or we missed a lesion.

It's very unusual for us to miss a

lesion actually. With experience, that doesn't happen very often. But we do get discordant results and we keep track of all of that because it's been suggested by the ACR that we do that. So I think most accredited facilities, Penny, you could probably tell me, if they voluntarily give that information. I know you're not gathering it as a big database yet but we were asked to give it and we do.

MS. BUTLER: Penny Butler, ACR. Yes, most of the facilities that do apply will provide us with the information, but we have not put it into a database that we can analyze it. We've told them that we're voluntarily requesting it from them with the thought about going back at a later date and reevaluating whether it should be mandatory or not.

DR. BARR: Penny, do you have any idea when you might get that information in an analyzable form?

MS. BUTLER: In a database? I can't give you an estimate right now.

DR. BARR: Thank you.

CHAIR HENDRICKS: I have a comment. Carolyn Hendricks, Panel Chair. In our community, the exact reverse of what Dr. Williams alluded to is occurring in that the very small number of breast surgeons are shifting almost all of their procedures to the radiologist, a higher level of confidence, wanting to spend more time in the OR. It's technically difficult to get access to stereo machines in our communities. The busiest breast surgeons are shifting their interventional work exclusively and just confidence in the radiologist.

So the exact reverse is occurring with the surgeons focusing on the primary breast surgery, allowing the interventional radiologists to establish the diagnosis of breast cancer which brings me to my comment. I'm hopeful that we really learn from the demonstration project from the MQSA data that possibly as the ACR accreditation data matures and you're able to compare the collaborative track with the individuals and facilities that are on the independent track that we might be able to compare those two and really determine whether the

collaborative approach is the best approach and whether the data is going to be superior in that track.

That is where we know there is an interaction between the radiologists and the surgeons as opposed to the physicians, either surgeon or radiologist that's operating independently to provide data for accreditation with a comparison between those two groups, the two sets of data. I'm not sure. The dataset looks small but it seems that you might be able to look at some of these quality indicators and some of the audit data and the complication rates and compare those two tracks.

DR. BARR: Dr. Hendricks, would you in your opinion then be in favor of waiting for that type of comparison and analysis to be done or going ahead and doing a regulatory program right now where we don't have a lot of that information?

CHAIR HENDRICKS: Carolyn Hendricks, Panel Chair. I do think as I'm listening to the discussion this morning that there is a difference

that this advisory committee should take as we approach mammography as opposed to the stereotactic procedure itself and the skill and to hold it to a little different standard. So I think the survey data is very important and that really is the only data that, other than anecdotal data, we've been able to look at. We need good outcomes data but I think we also need to acknowledge that significant deficiencies do exist even in the very select group of radiologists and surgeons that have agreed to participate in the accreditation process as it exists right now.

DR. BARR: So in your opinion, there's enough to proceed with a federal regulatory program.

CHAIR HENDRICKS: As we've heard from the speakers, from the representatives from ACR, it's very interesting of course to look at the audit data as it correlates with the pathology of the breast disease that's being diagnosed and it does sounds like that data is being collected and that would be very helpful. Dr. Monticciolo.

MEMBER MONTICCIOLO: Debbie Monticciolo.

I would just say that there is a tremendous body of literature on stereotactically guided biopsy and the successful rate of that procedure. Now what you're speaking of I think, Dr. Hendricks, is a little bit different in looking at sites that go for accreditation and why they fail, etc. I think that's worth looking at, but there is a body of data to show that this procedure can be done well and very accurately. That's been established in the literature for quite some time.

CHAIR HENDRICKS: Yes, I agree. Dr. Ferguson.

MEMBER FERGUSON: Yes, I'm asking for the sense of the committee and I've taken this all in and tried to read all of this. I agree with Debbie that on the wire localization, I believe, the equipment should be accredited. I think that you ought to be doing wire locs on equipment that you can do mammography on.

Also I have struggled with the mandatory accreditation for stereotactic and I think I come down on the side it should be required based on

personal experience, based on Melissa's comments that would be the mirror of mine at home and we saw this with MQSA. The people who don't go for accreditation are going to fall out or they're going to update their equipment and their education and their training and their quality control. I think that's what we want to see.

When Debbie mentions the volume of literature on stereotactic, I would bet a lot of money that that literature is coming from accredited facilities who have gone through voluntary accreditation and you won't see the information that you're looking from missed stereotactics because those facilities aren't doing the high quality of work that she's talking about. So I, as a sense of at least me on the committee, would favor regulation and on the issue of needle loc, I would say the equipment should meet the same standards.

CHAIR HENDRICKS: Any other comments from the panel before we break for lunch?

MEMBER MONTICCIOLO: A quick comment because we're waiting for lunch. With due respect

to Dr. Williams' remarks about needle localization, as some of you know, I've had several jobs because my husband has moved me all over the country. So I've practiced at Emory and Mass General and in private practice in smaller towns as well as in Texas and California and I have to say I've never seen wire localizations be an issue. What Dr. Williams is talking about is you can't get the wire close enough, you have to converse with your surgeon about how to operate.

But I've really never seen the actual placement of wire and obtaining a specimen if the surgeons and radiologists work well together that being a tremendous issue. I just want to reiterate. I think the equipment is an issue. We would really want to use certified equipment. But having an entire regulatory program for wire localization would be very onerous and I don't think it would be that productive.

DR. BARR: It's fine. I would like to perhaps continue a small bit after lunch with some more questions.

CHAIR HENDRICKS: Absolutely. I would like to thank the panel and the audience and all the participants for the discussion. We'll break now and then reconvene at 1:00 p.m. Off the record.

(Whereupon, at 12:03 p.m., the above-entitled matter recessed to reconvene at 1:04 p.m. the same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:04 p.m.

CHAIR HENDRICKS: On the record. Okay. Our meeting is back in session for the afternoon session. We're going to start out with a continuation by Dr. Helen Barr of our discussion of the Institute of Medicine Recommendations Regarding Interventional Mammography. Dr. Barr.

DR. BARR: Thank you. One thing I have neglected to do although I've thanked all of you is I did want to mention that this is Dr. Hendricks first time chairing this committee and I think she's an absolutely excellent job.

I'm going to try to lead the remainder of our discussion time by trying to summarize things I've heard and trying to conclude some discussions on them. One thing that I heard is that we should consider accrediting the mammography equipment that wire localization are performed on that there should no longer be an exemption that if you only use

equipment for those procedures that it is exempt from accreditation.

Dr. Finder, do you have any comments on what that would entail and what that would mean and perhaps we need some further clarification on what people's idea on that are.

EXEC. SECRETARY FINDER: Okay. I would like to ask the question when people said that they felt that equipment used for needle localizations should be accredited and I'm not exactly sure what they mean by that. It's one thing to use a piece of equipment that is also used for mammography where patients are going through that machine and you can actually generate enough images that can be sent for the standard accreditation.

But what do you do with a unit that is used strictly for needle localizations? Those machines under the current situation are not being used for general mammography. How would you accredit that type of unit?

CHAIR HENDRICKS: Yes, Carol.

MEMBER MOUNT: Carol Mount. You always

do your post films to show that your wire is in place. Couldn't you use those to view the two-view mammogram you do as your post wire position films as your films that you would send in and then your phantom image? Otherwise it could be the same.

EXEC. SECRETARY FINDER: Big difference in that at least the standard procedure, now you have to submit a bilateral mammogram, two views, of a normal examination or benign examination. That would require a change in the current accreditation process and review process and maybe we could get some comments from the ACR if they would be able to do something like that for those types of units.

MEMBER MONTICCIOLO: Could I make a comment also before we ask for comment from Penny? This is regarding a wire localization and how you would submit films from a unit that is being used only for wire localization. It would be difficult to use wire localization films because you couldn't achieve the same positioning. Getting the amount of pectoralis muscle on a patient that has a wire in her breast is not as easy. So there would have to

be some other accommodation.

MS. BUTLER: Sorry for coming in late. Penny Butler with the American College of Radiology. If I think I caught what you were talking about is asking for these dedicated wire loc units how would we test them under an MQSA approved accredited process?

CHAIR HENDRICKS: Yes.

MS. BUTLER: Let me ask our physicians on the panel. It's my impression that some of these may also be used for diagnostic films.

MEMBER MONTICCIOLO: In my place, we don't have any distinction. We only do our locs on accredited machinery. So the issue that Dr. Finder brought up was that if we decide to include machines that are only used for localization into the accreditation process how would they go about it because how do you submit films from that unit?

MS. BUTLER: It would be very difficult to do that because we really wouldn't have a process to evaluate it because we look at adequate film size and other kind of things. But it may be possible

under existing system if they also do diagnostic images there rather than just screens and not just MAGs but regular diagnostic images. They could send us the diagnostic images and then in that case they would follow that particular process that we allow in special cases.

DR. BARR: And I suppose if we simply said that these procedures had to be on an accredited mammography unit then the procedure would be the same. It would the same as it is now.

MS. BUTLER: Right.

DR. BARR: There would no longer be able to be a dedication of a machine solely for that purpose.

MS. BUTLER: That would have to be a decision that would have to be made.

MEMBER MARTIN: Melissa Martin. I would like to bring to your attention the fact that I know at least we have at least three surgery centers which have dedicated mammography units in it solely for localization procedures. They do not do anything else except wire locs in them.

I thought the suggestion was made that this be accredited for equipment only. So it would be very straightforward to require that these units pass the physicist annual evaluation. That's what I was hearing is that everyone was in support. That eliminates you having to evaluate the films. But it would still require to have a full physicist evaluation on the equipment.

DR. BARR: And it would require a change in the current accreditation procedures.

MS. BUTLER: Correct.

EXEC. SECRETARY FINDER: It's Dr. Finder. I just want to clarify. Everybody is listening to the same words and coming out with different ideas of what they mean. Accreditation is a defined process in a statute and the regulations and it involves the review of clinical images.

If you're talking about just meeting the equipment requirements and doing certain QC, that's not accreditation. That's something that doesn't exist right now but something that could be looked into. But again, when you use the terms these units

then should be accredited, it means something very specific that may not applicable to all the units that are out there and may not applicable to the current accreditation process that exists. I just want to make people aware of that.

DR. BARR: That's a good point.

MEMBER MOUNT: Just a comment about the films on a regular unit being used for wire. When we accredit stereo units, we're not doing the same positioning, the MLO and CC, to get all the anatomy on the film. You're positioning to get the area of interest. So if you were using a machine for wire localization, then too couldn't that just be you're looking at the image for the area of interest and image quality?

DR. BARR: Certainly, that's possible. The difference is that currently there is an accreditation program for stereo and there isn't for wire loc. So one would have to be developed if you were to go that way or as some other people are saying, are we simply interested that the equipment passes a physicist's survey and that's our bottom

line of interest there?

CHAIR HENDRICKS: Dr. Monticciolo.

MEMBER MONTICCIOLO: Just two comments. One is, I don't want to speak for Dr. Ferguson, both of us intended that the equipment pass the physicist's QA/QC. That's what we recommended for the wire localization. It's not a full accreditation process. We didn't understand that difference. Thank you, Dr. Finder, for that.

And the second I would just comment on what Carol Mount just said. The images that are submitted for the stereotactic accreditation program, and Penny can correct me if I'm wrong, are not assessed for positioning and they're not assessed the same way a clinical review is done. When we submit, we just want to indicate that we know where the lesion is and what the lesion is that we're going after. So the films are viewed differently. They accept copy films, not originals. So it's not held to the same standard as those that are used for diagnostic purposes.

CHAIR HENDRICKS: Yes. Dr. Williams.

MEMBER WILLIAMS: And furthermore, a lot of the stereo biopsy machines are small field of view. So they can't possibly visualize the entire breast anyway.

MEMBER MONTICCIOLO: The images that she's talking about that we submit, we do submit mammograms with our accreditation but they're copies and they're not judged the same way as clinical mammograms for accreditation.

DR. BARR: So, Charlie, if we would determine that a physicist survey is what we're interested, is there a way of incorporating that into inspection procedures without an accreditation program?

EXEC. SECRETARY FINDER: That's a very interesting question which we would have to talk with our lawyers about. We are bound by what the statute says and what regulations we would write. I'm not 100 percent sure that you can have something that gets certified without being accredited in some manner and how we would write that I don't know at this point. But it's something we would certainly

be able to look into.

DR. BARR: But it seems at least that we're hearing that it's the equipment itself and not the skill of the localizer that would be under evaluation.

MEMBER FERGUSON: That's how I see it. I would agree with what Debbie says.

DR. BARR: Okay. Thank you. For stereotactic, a couple things in summary. There is an existing accreditation program. There is a failure, a fairly significant failure rate, at this point, although we don't seem to know exactly what that failure rate means. We should be mindful and take into account of that. There does seem to be a body of literature that seems to indicate that this procedure can be done well and accurately and at least in the published reports is being done well and accurately.

So where does our interest lie in stereo? Is it the equipment? Is it the user? Is it the team? Where is our interest there?

MEMBER FERGUSON: I think it's the

entire team. I think it's the technologist. I think it's the physician. I think it's the equipment. I think it's the same as MQSA. I think we should be holding it to the same standard.

MEMBER MONTICCIOLO: It's Dr. Monticciolo. I agree with Dr. Ferguson. I think the program that's been begun in collaboration between the American College of Surgeons and American College of Radiology is a good one. It's the kind of things I would want to do anyway to insure quality. So I would support including that in regulation.

MEMBER MARTIN: I agree with Dr. Ferguson and Dr. Monticciolo. The program has been developed in collaboration with both the radiologists and the surgeons and it includes all aspects of the program, personnel, machines and procedures.

EXEC. SECRETARY FINDER: This is Dr. Finder. I have a question because there are a lot of similarities but there are differences between mammography and stereotactic biopsy. One of the

major differences that I see at least is the ability to obtain outcomes data in the sense of the audits that are currently being done in mammography and are being recommended to be increased by the IOM. They're trying to focus in on outcomes to a greater degree than we have in the past.

And a lot of the big problem with that is the difficulty in facilities being able to obtain the results from patients who they may have seen. That is not a big problem or shouldn't be a big problem in patients who are undergoing biopsies. So presumably for every biopsy done or attempted, there is a result whether cancer was found, whether it wasn't, where the results were concordant or discordant. Is that something that we should be looking at if we decide to go ahead with regulation in that program to a greater degree than we have in the mammography program?

MEMBER MONTICCIOLO: This is Dr. Monticciolo. While I don't agreed that the additional audit that's been recommended for mammography would be very useful simply because I

don't think there's any evidence to indicate it's going to change quality and it's going to be a burden.

On the other hand, I think you're right, Dr. Finder. For a stereotactic biopsy, I think we can be expected to get the biopsy results. I mean we're performing the biopsies and I don't know who else is going to get those results if we don't. Obviously, it can go the patient's primary care physician, but I check all the pathology as I think any person that does biopsies should be doing is checking their biopsy results.

And I think if you look at the American College of Radiology's accreditation program, the data that they're asking for, requesting but not requiring right now, is a very good way to audit those programs. It's a reasonable request. They ask for rebiopsy rates, discordance, hematoma formation, those type of things. It's very minimal. It's the type of thing that you would want to do to insure what you're doing is accurate and correct anyway.

So I think we could make that a mandatory data collection without much difficulty. I wouldn't have much heartburn about it. I think it would probably be a good thing.

MEMBER FERGUSON: And I would agree. I think that information is readily available and it's right there on the spot and you should be checking it. I don't see where that would be an undue burden.

DR. BARR: And, Dr. Ferguson, who would be checking that? The accreditation body would require it. An inspector would look for it.

MEMBER FERGUSON: It would gathered by the person performing the biopsy and then submitted to the accrediting body.

DR. BARR: Would there be an audit that the inspector, like for MQSA, would look at? Do we envision an inspection procedure for stereo?

MEMBER FERGUSON: I would envision the audit data being collected and submitted and you're going to have a fabulous data bank with accurate information.

DR. BARR: I wish we had that now.

MEMBER FERGUSON: Yes.

DR. BARR: Does anybody have comments about inspection in stereo? Do we envision that? What do we envision that looking like?

MEMBER MONTICCIOLO: I'm not sure if I can envision what it would look like. I would say that it would be nice if the inspection process itself were minimally disruptive on the practices because it does take a lot of time to prepare for inspections and to set the room aside and to do those types of things. It's the same issue with mammography of course.

I would envision the data for biopsy success to go to the accrediting body to be assessed. It seems like an inspection probably could be done with minimal disruption though.

DR. BARR: Thank you. Any other? Charlie, do you have any other, since you are always good at raising the issues, issues on the stereotactic side either to accreditation, certification, inspection that you would like some

discussion on?

EXEC. SECRETARY FINDER: Yes. Actually I had sent around a question or a series of questions before the meeting to the committee members and I just want to make sure that we've actually answered some of these questions. And my first question there was have we clearly defined what we consider the problems with interventional stereotactic because I do think that if we believe that the problems are diffuse, we have to have a diffuse type of program where we look at everything and not focus on any one area. If we believe that the problems are more focused in one area whether it be equipment or personnel or audit or whatever, then if we plan a accreditation inspection and certification program, we should try and focus in on those areas. Just my own personal opinion in the mammography program, we focus a lot on equipment and I think while there were some problems there where now getting a state of diminishing returns on that and maybe we would be better focusing on some of the other areas as recommended by IOM.

I'd like to go with that same type of philosophy if we're going to regulate stereotactic. So my first question would be what do people here on this committee really think the problems are and then that will help us direct our focus on what we should do about them. So if anybody has any idea of that.

MEMBER RINELLA: Diane Rinella. Can someone from the ACR let us know as far as the facilities that failed accreditation what percentages of what they failed, films they sent in or what the failure rates were? I mean we got the overall percentage but was it broken down?

MS. BUTLER: Penny Butler, ACR. We did break it down between clinical, phantom and dose. I don't have a further breakdown at this time with regards to calcs versus mass or fibrous specs masses on the phantom.

MEMBER RINELLA: With regards to the necessary requirements of the technologists and what not to perform stereo with the radiologist and all the continuing education and all that, is that

listed in here?

MS. BUTLER: No, it's not reflected in there because they don't proceed unless they meet the personnel requirements.

MEMBER RINELLA: So that's not an issue with accreditation for stereo units.

MS. BUTLER: It's not an issue because if they provide a name of an individual and that person does not meet the requirements, we tell them they cannot proceed with accreditation and use this individual to perform the stereo procedures and be accredited. So sometimes they actually shuffle people around on their staff in order to proceed with accreditation.

MEMBER RINELLA: Okay. So then to get to that point then, it always has to be something clinical.

MS. BUTLER: Right.

MEMBER RINELLA: Or with the phantom.

MS. BUTLER: Right. It's the testing we call it.

MEMBER RINELLA: Okay. So the machine.

CHAIR HENDRICKS: Yes. Carolyn Hendricks. I have a follow-up question please. Just for the panel that as a panel if we could hear in terms of the background of the development of this accreditation program. Dr. Finder was concerned about the balance and the emphasis on the technical aspects as opposed to the clinical. So I'm curious in your instances you were accrediting these facilities whether there was a waiting and whether the clinical failure had a higher weight than for example the technical failure. As you guys were developing this procedure, how did you weigh those two features of this accreditation process, clinical and technical?

MS. BUTLER: There is not a waiting. Basically you have to pass all aspects in order to pass accreditation. So you may not pass in the phantom which may be considered a technical aspect and pass in the clinical and we would not grant accreditation. You would have to take corrective action and repeat the test so all aspects pass.

CHAIR HENDRICKS: Thank you.

EXEC. SECRETARY FINDER: This is Dr. Finder. I just want to ask a question. In terms of personnel qualifications, my understanding, and correct me if I'm wrong, is you basically accept an attestation that these people meet or do they actually have to submit documentation of the qualifications?

MS. BUTLER: They have to submit an attestation. But we also do do site visits and they have to be able to show us the documentation once we show up.

CHAIR HENDRICKS: Thank you. Yes, from the audience.

MS. WILCOX: Pam Wilcox, ACR. I think going back to your question about personnel while it's not a pass/fail criteria because they're not even eligible to apply if they don't meet it, that still raises the bar. Those people as we saw in mammography, some people got out of the business because they didn't want to go through the training or they didn't want to buy adequate equipment. So it does have an impact before they can even get into

the process. Thank you.

MEMBER MARTIN: Melissa Martin. Again being a consulting physicist, we see all ranges of the equipment and it is a state requirement that there be a physicist evaluation in California annually. It is not uncommon that a unit is pulled out a hospital, a major medical center, and bought by another person and reinstalled in their office.

That equipment definitely would not meet state-of-the-art requirements. So your question as to what is the problem, I think it is a range of problems and that's what you will find when you start going and evaluating all the facilities.

I would highly recommend too that the requirement that it be a mammography trained technologist be the technologist used in this procedure. The biggest problems I have seen are those facilities that do not have a mammography technologist working with particularly the surgeons. If you don't have a radiologist and you do not have a mammography technologist, you basically have people that are very untrained or just not cognizant

of dose requirements or dose problems and the idea of what significance it may be if you repeat that film or that image many times.

DR. BARR: Thank you. Yes, we see similar issues with interventional fluoroscopy procedures and lots of other areas. Do you want to keep going with your questions, Charlie?

EXEC. SECRETARY FINDER: I guess the major question has been answered, what problems exist, and it sounds like everything a problem in terms of equipment, personnel, audit. So we can't focus on any one area. At least that's the impression I'm getting from the committee.

DR. BARR: How come the data is so good if everything is a problem?

MEMBER MONTICCIOLO: Can I just make a comment to that?

DR. BARR: Yes.

MEMBER MONTICCIOLO: While I support this as you know, I'm sorry, it's Dr. Monticciolo, I don't think we know how serious a problem it is. We don't have that data. I think we do stereo pretty

well where I'm at and I know a lot of people who do it well. So I would say that the reason I support these standards is to make sure that everyone who is doing it can meet a certain standard. I agree with the comment about having a mammography technologist involved. That would be crucial, I think, to make sure these procedures go well.

DR. BARR: Thank you.

EXEC. SECRETARY FINDER: I have a question about that and maybe somebody from ACR can address it. We have heard in the past about technologists who have gone into the stereotactic field who spent a lot of their time doing stereotactic and they have the issue about keeping up with requirements if they're also going to be MQSA certified mammo techs. Is there any comment or enlightenment from your experience in the voluntary program if that's a problem or not?

MS. BUTLER: Penny Butler, ACR. So your question is regarding a mammo tech who does stereo and staying up with mammo qualifications?

EXEC. SECRETARY FINDER: Right.

MS. BUTLER: We actually brought this issue up to our committee a couple years ago after receiving a request from I think it was just one facility regarding a stereo dedicated technologist who didn't want to maintain mammo and the committee felt that it was very strong for the individual's qualifications to maintain the small number really of examinations that MQSA requires for mammography in order to really put the entire examination together. So they did not want to change the requirements.

EXEC. SECRETARY FINDER: Thank you.

MEMBER MONTICCIOLO: This is Debbie Monticciolo. I would just reiterate or support what Penny says. The minimum number of films a technologist has to do is not that onerous and I think if the technologist is going to do a good job at doing stereo they have to be familiar with how to image and continue to do standard imaging. I would be interested in what the technologists have to say about that but I would think you would want to be able to do both to keep your skills up.

MEMBER RINELLA: Diane Rinella. I absolutely agree with you. It is a minimal amount, number of examinations, to do per year and you need to know how to manipulate the breast correctly and if the only thing you're going to be doing is stereo, I don't feel it's enough as far as your technical expertise.

MEMBER MOUNT: Carol Mount. I totally agree with that. I think they should be able to keep up their minimal 200 and continue to do stereo. They should be able to do them both. It's very important like Diane said to be able to do both.

DR. BARR: Thank you.

MR. FLATER: Don Flater with Iowa. If you want to refer back to the Iowa rules, it does show how much they have to do plus we also require that they be a general diagnostic radiographer in the State of Iowa. So they don't have any trouble meeting those. We chart 12 and then three every year thereafter. So it has not been difficult for our technologists to maintain the requirements. We didn't have any that dropped out up to that period

of time.

One other point that I didn't bring up that I think is germane and that has to do with the issue of suits against radiologists and folks like that. We have had none in the stereotactic area and I know that for a fact because that comes through our board of medical examiners and those kind of things since the program started nor have we had any lawsuits against radiologists as with regard to our mammography program.

DR. BARR: So we're talking about the technologist. Then we would be requiring, if we required a person to be a technologist and they were hired by a surgeon, that they would have to find some way then to perform the number of mammograms that are needed and presumably the surgeon would have to allow them time to do that. Dr. Harrison, are you there? I would be interested in hearing a breast surgeon, another breast surgeon's point of view.

I think this is an important issue because this would bring surgeons into the realm of

federal regulation which nobody but a radiologist has heretofore had the privilege of. So I think it's important to get some of these opinions.

MEMBER HARRISON: Yes, I am. I'm sorry. I was talking to you on mute. I'm here.

DR. BARR: That's the way we generally like our surgeons to talk to us.

MEMBER HARRISON: I was trying to figure out why no one could hear my response. Can you please repeat the question? The audio is very -- I can hear very well sometimes and not so well others.

DR. BARR: Yes, we so appreciate you trying to do this and bear with us. If we go ahead and lift the exemption for stereo, then surgeons would become part of a federal regulatory process which heretofore they have not been. So I'm interested in getting as many opinions from surgeons, particularly breast surgeons, as to how this would affect their practices, what they think about this.

We just discussed that if there was a requirement that a mammography technologist be

involved with stereo that they would still have to keep up their mammograms. So if a surgeon hired a technologist, he or she would have to --

MEMBER HARRISON: May I comment?

DR. BARR: You go ahead. Shoot.

MEMBER HARRISON: I personally am in a very comfortable situation. My hospital has a breast center where I work very heavily with the technologist and the radiologist. So I do my own stereotactic core biopsies but clearly all the films are read pre and post and the post biopsy film is read by the radiologist.

I don't believe that those of us who have committed to this in practice will have any problem whatsoever being regulated at all. As a matter of fact, I think we'd welcome it. We all wanted to be more involved and tied to the radiologist because there was a time when this was a turfing battle and it should not be a turfing battle. So I would welcome that and I think all of us who are committed to being "breast surgeons" would certainly comply and welcome it.

DR. BARR: Thank you very much.

MEMBER HARRISON: Hello. Are you there?

DR. BARR: Yes. Thank you very much. That's very helpful. Thank you. Charlie, did you have any more questions on your roster?

EXEC. SECRETARY FINDER: No.

DR. BARR: I did hear one of our public speakers talk about the whole chain of not only breast imaging and breast treatment as quality. I just wonder where do we draw the line. Is the line overdrawn? Where are the pathologists? Do we need to make sure under federal regulation that they know what they're doing? Do we need to involve the surgeons not only in stereo but in excisional biopsy? How about the oncologists who are treating the patients? How far do we go along this chain of diagnosing and treating breast cancer with federal regulation? Dr. Ferguson.

MEMBER FERGUSON: Ferguson. I think Dr. Finder set out in the beginning that our panel, we strictly deal with imaging of the breast. And so I don't think pathologists and oncologists are going

to fall into the purview of what we're looking at here. I think he made that very clear to me at least. Is that right?

EXEC. SECRETARY FINDER: Right. It's Dr. Finder. That is correct and it does bring up another interesting point. Because while the IOM recommendations talk about a breast imaging quality standards act, that does not exist at the present time. So it is an issue that I think we should maybe touch on very briefly what people think might be the consequences of regulating stereotactic procedures, mammographically guided stereotactic procedures, in an environment where there is no control over ultrasound or MRI biopsy and again the regulation of even needle localizations wouldn't be as comprehensive as for stereotactic.

Does anybody think that what we might end up doing is just moving people over from the stereotactic into either ultrasound biopsy or moving them out of needle guided biopsies back to open biopsies using needle localization? Could we actually be pushing things in the wrong direction if

we can't control everything? Just a point for discussion.

MEMBER MONTICCIOLO: Dr. Monticciolo. I think it's hard to tell. It's the unintended consequences of making these types of decisions. I don't think that you'll move many people from stereo into ultrasound or MR guided biopsies simply because calcifications are not very readily seen on those modalities and we use stereotactically almost exclusively for calcifications now because we tend to see masses pretty well on ultrasound.

But the issue of moving probably primarily surgeons doing these techniques if they can't qualify for stereotactic back to open biopsy is probably a read concern. Radiologists don't do open biopsies. So they're not going to be pushed in that direction. They're either going to get pushed out of it or they're going to do it to meet the regs. But I would say it probably is a legitimate concern, but I don't know the extent of the problem or what the extent of the problem would be.

CHAIR HENDRICKS: From the audience.

MS. WAGNER: Judy Wagner.

CHAIR HENDRICKS: To the microphone please and then reintroduce yourself to all of us.

MS. WAGNER: Judy Wagner, R.N. That is exactly why I am speaking to women's groups next week. Next month, I have four meetings with women at a bank that has contacted me to talk to their women. That's why when women hear they need a biopsy, they're going to say, "I want a needle." And I've given you some documentation of a questionnaire that I handed out and when I gave my talk those women got that message and I hope that all of them will tell 20 other women.

CHAIR HENDRICKS: I'll comment, Carolyn Hendricks, Panel Chair, on the concern that regulation of a stereotactic biopsy procedure might drive radiologists and surgeons to perform fewer stereotactic biopsies in favor of open biopsies. I think that won't occur for the fact that we have not been able to make a dent in the open biopsy rates in the United States for some time even with the advent of the stereotactic procedure.

What I think it might do regulating this procedure because it is hinging on breast imaging which is our mission is that it might make radiologists and surgeons more selective. We really want a good candidate for a stereotactic biopsy. Once that decision is made, that's when the process gets started. So if a regulatory piece makes physicians scrutinize that initial decision, "Is this woman a good candidate for a stereotactic breast biopsy" then we would have achieved that goal and improved that quality of the procedure.

MEMBER MARTIN: Melissa Martin. I thought the other item of consideration was the recommendation from the IOM report that the ultrasound guided procedures also be required for accreditation which if you do them in conjunction with each other, then you're not going to be necessarily driving patients from one to the other. It's the radiologist's choice for the performance of the biopsy procedure because both units would be required to be accredited.

EXEC. SECRETARY FINDER: It's Dr.

Finder. The difference is that under the current situation, under MQSA, we do have the ability to regulate stereotactic biopsy. We do not have the ability to regulate ultrasound. In order for that to occur, Congress would have to change the law and then we could work on it.

If you're saying they'd have to be done at the same time, then we'd have to wait until Congress does something before we do anything. But there will be this asymmetry if we decide to go ahead with this just because of the way our current authority is created.

DR. DOWLATSHAHI: This is Dowlat from Chicago. I think you are moving very fast for me. I don't want to go back and be killed as a messenger. There are a lot of surgeons in the country and especially the American breast surgeons who would like to hear your opinion before you come to a definite decision. As I said, I didn't have enough time to search around to get the opinion from everybody but it would be good if you gave the College of Surgeons as well as the Society of Breast

Surgeons a chance to come up with some ideas or suggestions that don't come to me right now. That's No. 1.

The other caveat that I wanted to mention is that the speaker said we want needle and not knife. Well, that has now become very debatable because some of the big needles these days require an incision and we even go in with a radio frequency device and carve out the piece of breast tissue.

So technically the needle is not what it used to be. A small 16 or 18 gauge is now eight or nine and as I said, sometimes you have to make an incision. So the difference between the needle and the knife is not that well defined and I just wanted to tell you as a person who does these biopsies to let you know that there are a variety of issues which I would like to take back to the people who are practitioners in this field.

CHAIR HENDRICKS: Any other questions from the panel or the audience on this topic of the IOM? Yes?

MR. MOURAD: Wally Mourad, FDA. I don't

want to jump the gun on inspections before we even write regulations but as Dr. Monticciolo mentioned be easy on the inspections, do not make it onerous and laborious. What do you mean by that? Should we cut down on the scope or minimize the questions? Could you explain a little bit more?

MEMBER MONTICCIOLO: This is Dr. Monticciolo. I'm a veteran of these inspections in different states as I indicated before and sometimes it's very smooth. We've generally been in compliance. That's not been the issue but sometimes it just takes longer for inspectors to get through all the equipment, records and we have satellites that have to close down for a full day. So they lose all those patients. They can't do patients.

So it's just a matter of taking it into account and the cost of doing this. For the facilities, it can be extremely difficult and we've had inspectors at our site especially if it's an inexperienced inspector for a couple days for the five units and it's very disruptive when you're trying to do 100 patients a day and procedures and

you have to run around and get everything ready and close down and it can be onerous.

It's only once a year. That's the good news, but it can be difficult. So if one more thing is added to that, it's just a lot for the technologists to have to prepare and for the patients that we're also trying to service that day. That's what I meant.

DR. BARR: I think you raise some good points and it's interesting that we've heard a lot don't give us anymore regulatory burden, don't spend anymore time in the facility than you've already been spending and here we're talking about additional regulatory burden and then additional time in the facility. So it's interesting. It goes against some of the other things that we've heard.

MEMBER MOUNT: Carol Mount. I think the difference is none of us want any more work. None of us want any more burden, but I think we all want good patient care and the bottom line is quality not so much the burden. Yes, we don't like it but we will accept it if we can raise the bar.

DR. BARR: Thank you.

MEMBER MONTICCIOLO: Dr. Monticciolo. Just along those lines, I would say that's a very reasonable assessment, Dr. Barr, that when we go for accreditation we have time to gather things and the clock start running and you have to get the films but you can spread that over. If you have three days when you have a lot of patients cramming into your center, you can maybe do some of your ACR accreditation paperwork on a day that's not as busy.

But for inspection, there's no give and take. It's there and so that is a little bit different issue, accreditation versus inspection for our time.

CHAIR HENDRICKS: Thank you. Yes, from the audience.

MS. WILCOX: Pam Wilcox, ACR. I wonder if the state inspectors and the physicists could talk to the inspection process for stereo in terms of the inspector having to have access to the unit. There's a difficulty in mammography when you have to not do patients. But if a woman is scheduled for

a biopsy and has to be cancelled, I think the implications are more significant.

MEMBER MARTIN: Melissa Martin. I would like to think that the process that would be developed for inspections will be more allowing the proposed line of what I think is coming along for all the mammography inspections where it will be basically more of an inspection of the physicist report if the physicist report is current and there would be more minimal time, if any, for that inspector to be on the actual machine.

The only thing I can see an inspector actually ever doing in a biopsy unit is having the technologist take a phantom film because that would not even require the inspectors to be trained to operate the stereotactic units. And that should be minimal. It might even be a recommended procedure that if the technologist could take a phantom film the morning of the inspector's arrival and have it available for review, that would be acceptable. It's just a suggestion, but that way it wouldn't impact patient care.

DR. BARR: Thank you.

MEMBER PASSETTI: I think you're already moving in the right direction as far as the inspections go. You're looking at not taking dose measurements. You're looking at simplifying the CE so the inspectors, it's easier for them to check. I think if we're going to add some regulatory requirements in the high risk areas, you just need to consider continually looking at your inspection process to make sure you're looking at the important areas and cut back on those areas like you said the inspector doesn't need to do while they're in there or they can do off to the side looking at physicist's reports and those types of things. So I think you're starting to head in that direction and I'll just encourage you to keep going in that way.

DR. BARR: Thank you.

CHAIR HENDRICKS: From the audience.

MEMBER WILLIAMS: Thanks. But, no, this is Mark Williams. I just wanted to agree 100 percent with what Melissa said. It think that's exactly the right approach and the way that things

are going already and I think that with the physicist report in hand it's going to alleviate essentially all of the physical tests that the inspector would have to do.

MR. FLATER: Don Flater from Iowa. It may do that but what we're going to have to be very careful of is the legal aspect of this and what's going to happen relative to our records and what the state is attesting to and the responsibility that they're taking on. So we have to be careful.

I'm not saying that we can't do that. But all of a sudden, do physicists want to become state inspectors and have that legal problem that they may have to deal with if we have to go in and have to actually enforce our regulations and what kind of a liability does it put on them? Are they now state employees? We have to ask some attorney generals questions and ask whether or not they come under the umbrella of the state being the regulatory. If somebody makes a mistake who's responsible for it?

I think there are a lot of questions you

have to be careful in the inspection process and what we're going to do. I'm not disagreeing with what you're saying. I'm just saying be careful because as we know, our attorneys can make different decisions and when you have 50 state attorney generals to deal with plus you have the federal folks to deal with on the legal side, there are some questions that probably really need to be considered very closely.

CHAIR HENDRICKS: Carolyn Hendricks, Panel Chair. I have a quick follow-up question, Mr. Flater, related to how you handle in Iowa the mandatory program currently in place. How do you handle the down-time and the inspection time when you're taking a stereo unit off-line to inspect it and accredit it?

MR. FLATER: We call our facilities five days ahead of time even though our stereotactics don't fall under. We do the same thing that we do on our MQSA. If there is a problem, then we adjust our schedule to fit their schedule so that they don't have down time. There are facilities that

doctor referred to that have 100 patients per day. We go into them at night and we actually do the inspections at night so we do not disturb the patient flow.

That's one thing that the Department of Public Health gets really excited about is if we get a call from a facility and say we're doing something that's a problem with health. So we make adjustments for our schedules. Our people are not on an 8:00 a.m. to 4:00 p.m. basis. If they have to go in at 9:00 p.m. they have to go in 9:00 p.m. That's just the way it works. That's the way it's been for all our regulatory programs even our NRC programs and our inspections and those kinds of things.

CHAIR HENDRICKS: Thank you.

DR. BARR: I think we're all, as several people have commented, our goal here is quality. I have just as a public health person need to continually raise the question about whether federal regulation is the only way to achieve that quality. How about in the area of breast ultrasound and I

sort of disagree with the statement that we don't need to look at the whole chain. To me if we're ever going to make the ultimate dent in breast cancer, it's the whole chain that needs to be looked at.

I wonder why we concentrate on certain pieces of it. We do because the moon and stars gave us MQSA and that's what we do at the moment. But since it is in the IOM recommendation, what about breast ultrasound? What about breast MRI? What about a statutory change to include all of breast imaging or perhaps beyond?

CHAIR HENDRICKS: Carol Hendricks, Panel Chair. I think from the information that we've heard for the past two days it seems that it is premature to incorporate MRI imaging or MRI guided breast biopsy procedures into any form of regulations at this point in time.

DR. BARR: What do you think about breast ultrasound where there is an accreditation program in existence? Although I don't know. ACR, is a breast ultrasound non interventional? Does it

deal with any interventional, breast ultrasound?

MS. BUTLER: Penny Butler, ACR. It is both non interventional and interventional. There is a module that they can apply for for interventional.

DR. BARR: Thank you. And I certainly agree from what I've heard. The MRI issue seems to be off the table for the moment, but the breast ultrasound, one of the arguments I've heard for stereos we have an accreditation program. Therefore, we climb Mt. Everest because it's there. We have this accreditation program. What do we do with it?

MEMBER RINELLA: As far as breast ultrasound is concerned, there is just so much variability out there throughout all the facilities that I've seen and I feel very strongly that it should be an accredited modality because there just isn't enough consistency from how they're done and who is actually doing examination because in some facilities these are not even ultrasound technologists that are doing the exams.

DR. BARR: Thank you.

MEMBER PASSETTI: Bill Passetti. I'm not sure how many states you contract with to do the MQSA inspection. I don't know if you have that right off the bat.

DR. BARR: Basically, from moment to moment, I don't know but I think there's maybe four or five states that we do not contract with.

MEMBER PASSETTI: I guess my only caution or concern with ultrasound is not all states have the authority or the ability to do inspections under contract in that area. So that would fall more into the FDA's responsibilities. I just don't know. Currently in Florida, we have authority in the non-ionizing area but we don't have any regulations or inspection authority. So that could be an issue if you got into the inspection of those types of units.

DR. BARR: If it were an MQSA type program, you would have the authority. You wouldn't need state authority. But are you more saying that since there aren't many states that probably inspect

ultrasound, the expertise wouldn't be there.

MEMBER PASSETTI: The expertise and maybe the willingness to get into that area.

DR. BARR: Thank you. That's a good point. Linda.

MEMBER PURA: Linda Pura. I would think if we're using the gold key of quality then we are moving from the MQSA to breast imaging mammography regulations and ultrasound would certainly fall under there because there are many variants in how it's done and who does it from what I see out in my particular practices in the community. So I would very much like to see not only stereotactic but I would like to see ultrasound also under regulation.

DR. BARR: Thank you. Don Flater.

MR. FLATER: Don Flater from Iowa and I just want to emphasize what Bill said. The magic line for us in the State of Iowa at the current time is non-ionizing versus ionizing. We do not cross that barrier. Dr. Barr, I would not be able to inspect them because if they don't have the authority to go in the facility even if there's a

federal law, it doesn't make any difference. We cannot cross that barrier. So we would have to get new legislation not that it's not that difficult to do but we would have to do that.

DR. BARR: Thank you.

CHAIR HENDRICKS: Carolyn Hendricks, Panel Chair. If I could put Penny Butler from ACR on the spot for a moment because I feel like we've not been using some of the information from your very important survey data on your accreditation on stereotactic procedures. But I feel like I really don't have adequate information on where we stand in terms of ACR and the ultrasound process. Where do we stand right not in terms of accreditation for ultrasound procedures under ACR?

MS. BUTLER: Penny Butler, ACR. Unfortunately, I didn't come prepared like I did for stereo with all the numbers and don't quote me and I'd certainly be happy to provide this information to you later. But I think it's on the order of 300 to 400. Does that ring a bell? Okay. Three hundred to 400 facilities that we accredit.

By the way, we don't accredit, it's not unit based like we have in stereo but it's facility based. So they may have multiple units but we would accredit the entire facility's practice. Unfortunately, I cannot break it down right now into the number that we accredit for interventional. Certainly, not all facilities going through breast ultrasound accreditation will also accredit in interventional but my gut feeling right now is it's most of them.

Pass rate, again, I'd have to go back and look at the numbers. It's probably about the same order but I really can't tell right now. So what else do you want to know?

CHAIR HENDRICKS: Thank you.

DR. BARR: Perhaps at the next meeting we could have a presentation on breast ultrasound.

CHAIR HENDRICKS: Yes. Carolyn Hendricks, Panel Chair. I think that that would be, I know that you want information from this panel as we sit on our opinions related to ultrasound. But I don't feel that we have an adequate information base

at this point in time. Thank you.

MS. BUTLER: May I ask a question now?

DR. BARR: Yes.

MS. BUTLER: Thank you. One of the questions I have is obviously MQSA refers to x-ray and Breast Imaging Quality Standards Act would apply to a change in the legislation in order to grant anybody authority to take that next step. Does this body here have the, is there an intent from this body to provide Congress with a recommendation one way or the other or is this on the table? I'll be quiet now.

DR. BARR: You're absolutely right, Penny. It would require a statutory change which logistically at the time of reauthorization would be the easiest time to get that. I think I heard Dr. Hendricks say that we probably don't have enough information to make a full recommendation on ultrasound at this point.

CHAIR HENDRICKS: Yes. Carolyn Hendricks. I welcome input from the other members of this panel of course on it especially the

diagnostic radiologists.

MEMBER FERGUSON: I'd like to say I think that we need to be moving towards an accreditation program in ultrasound. I don't think we have all the pieces yet. What I wouldn't want to do is to somehow be distracted from the stereotactic issue we've been talking about and say, "Let's do ultrasound and do it all at one time and put off what we're moving towards." I feel very strongly we need to move towards the stereotactic process. We need to moving towards the ultrasound accreditation process as well would be my feeling.

CHAIR HENDRICKS: Dr. Monticciolo, comment?

MEMBER MONTICCIOLO: Yes. Dr. Monticciolo. In my experience, the comments that Diane made are accurate. Ultrasound is really all over the map and we see a lot of use of ultrasound that's inappropriate and miss diagnoses all the time. It's in variable hands. It's not done by people who are trained to do it and they think because the breast is an external appendage it ought

to be easy and it's not. So I think that some type of improvements certainly would be welcome.

I'm a little bit hesitant only because as a breast imager I already feel overburdened. So I'm little bit concerned about that. But I think Dr. Ferguson's comments are good ones and I am in favor of quality and I don't see another way around it. I think we're moving in that direction.

The ACR Breast Ultrasound Accreditation Program is a good one. I will say I'm on that committee. So you should know that. The committee members are really good, but I also review for that program. So I'm familiar with it, but it's a difficult issue. I don't know that we have enough to go ahead to make that mandatory yet. Obviously we can't because it requires a change in the law. But certainly there is a tremendous variability in breast ultrasound right now and it really does need a look.

MEMBER MOUNT: Carol Mount. I totally agree that breast ultrasound is an area that should be accredited. It's probably not quite ready yet as

there are some things that have to be put into place. The only question I have and since you are on the committee is we accredit as Penny said the facility and one facility may have several ultrasound units. So if they are sending in their picture from their best unit, they still may be using substandard units to do full breast ultrasound or whatever. So that might be something that could be addressed and maybe the committee is looking at that as well.

MEMBER MONTICCIOLO: This is Dr. Monticciolo. I'm sorry I mentioned I was on the committee because it's letting Penny off the hook now for answering these questions. That might be an issue but I suppose we would have to look at that. In my experience, the reason people fail is there's some poor image quality but that's controlled by the operator. And my experience shows that if the operator doesn't know what they're doing, they need to change their game and they're just submitting images that obviously would be poor for diagnosis and it's pretty apparent. But I suppose it's

possible for somebody to do really well on one ultrasound machine and not do well on another. But I tend to see people if they don't know how to scan on one machine, they're going to do poorly on different types of machines. So I'm not sure how much we need to do with that.

DR. BARR: Is it reasonable to sum the ultrasound discussion to say that perhaps we should be moving in that direction but that at future meetings, we should plan some presentations and further discussion?

MEMBER MONTICCIOLO: I would agree with that.

DR. BARR: I'm interested to know if the voluntary accreditation program if all of a sudden people see the writing on the wall for regulation and a much larger percentage of the stereotactic units out there were to get accredited and the failure would go down, we haven't seen a voluntary accreditation program work very well yet. If we saw that, would that make any difference in your recommendations related to stereo?

MEMBER MONTICCIOLO: I'm not sure I understand the question. You're saying would that make me feel like it's working? Is that your question?

DR. BARR: Right. Would you still think you need federal regulation if we were seeing a voluntary accreditation program that had a large percentage of the units applying and passing accreditation.

MEMBER MONTICCIOLO: Oh. It's Dr. Monticciolo. That's a very good point. I think if we saw a large percentage doing it voluntarily, it probably would not need regulation. I just want to make a comment that Melissa mentioned earlier that a lot of programs use the materials but don't apply for accreditation and I am wondering and maybe Penny would have some information on this. A lot of places don't want to spend the extra money for a voluntary program especially in the breast imaging section.

For example, when I came to Texas, I said we're going to get accredited for ultrasound

and stereotactic and the administrator said, "How much is that going to cost? We don't need to do it so we're not doing it." I said, "We're doing it." And we had this little discussion with the chairman and I got my way. That was mainly because I was new. There's that little honeymoon period there.

But I think my administrator was not opposed to us having high quality stereo. They wanted that but they didn't want to spend the money. So I'm not sure how many units. People might be doing good work but just getting that little stamp because they're trying to avoid paying.

CHAIR HENDRICKS: From the audience.

MS. WILCOX: Pam Wilcox, ACR. I'm sorry that we don't have the numbers of people who bought the stereo manual that didn't apply for accreditation. I couldn't pull it out of my hip pocket.

But just going back historically, and Dr. Barr's probably going to shoot me for this, but I'll take my chances. When the Mammography Quality Standards Act was passed at the time it was actually

passed, it wasn't implemented for two years. About 70 percent of the facilities doing mammography in the U.S. had applied voluntarily. My guess is that other 30 percent probably never would have.

And in fact, although they knew that there was a two year deadline to get accredited, in the last six months before the law went into effect and they had to be accredited, we had a huge bolus of sites that waited until the very last minute and we had to work closely with FDA to have all kinds of extension procedures so people didn't have to shut down because they waited until the day before the deadline.

We also heard before this committee when it was composed of other individuals that if 90 percent of all the stereo sites in the country voluntarily got accredited, then we wouldn't need to regulate that. As I recall, that is now nine years ago. So my perspective is it's not going to happen unless there's a mandate.

DR. BARR: No, I'm not going to shoot you because as I've said we haven't seen a voluntary

program that that's happened. Just as a federal regulator, I'm trying to get to the point of if we ever saw that, would we still need federal regulation or would that be good enough for us? Thank you. Very helpful.

CHAIR HENDRICKS: We have time for one or two more comments and then we'll move on.

MR. FLATER: Flater with Iowa. I've been in this business now 41 years and looked at every side of radiological health that there is and I can tell you that the good people are going to work the programs. The ones that are going to provide nasty services are not going to do it unless you hit them with a big hammer and you force them to do it. So the question that you have here is do we want to let the ones that are going to give the bad services and everything go ahead and do it.

You don't need to talk about the good guys that are going to go and I'll bet you every one of these people on this panel are ones that would fall right into the voluntary system. But the bad guys will not. Ninety-five percent of the people

that we set a regulation for qualify for it, do everything they can to meet it. It's that nasty five percent that gives you the bad time.

CHAIR HENDRICKS: Thank you. One final comment from the audience?

MS. WAGNER: Judy Wagner. In response to your question about ultrasound accreditation, in my article that I handed you out this morning, I believe I took out north, south, east and west and I compared stereotactic accreditation with ultrasound saying in your area of the country, how do you fit. The reason being is in Wisconsin there are ten hospitals or facilities that are accredited for stereotactic and six for ultrasound. So in my article that I wrote, I said, "Where do you fit?" You can look those answers up on the wonderful ARC.org under Facilities.

My other question, and Dr. Finder has brought it up to me and I've heard it from other people, if you mandate stereotactic, then they're going to take people across the street to their little clinic and they're going to do ultrasound.

So are you really doing the patient a service?

That is why I believe and I've talked Senator Mikulski's aide about this is that we need to make the umbrella BIQSA and as soon as possible give standards for ultrasound so this doesn't happen because how is the patient going to know when the doctor says, "Honey, come here. I can cut that out for you." You say, "Yesterday."

DR. BARR: I wonder about appropriated money for all this and what the interest from Congress is going to be in appropriating money. I also had another thought but go ahead, Debbie, since I can't think of it.

MEMBER MONTICCIOLO: Dr. Monticciolo. With all due respect to the member from the audience, if I have a choice between doing an ultrasound guided biopsy and a stereotactic biopsy on a patient, I'm going to pick ultrasound every time. It's more comfortable for the patient. She's laying on her back instead of on her stomach. It's easy. You can see the needle moving real time. It's a tremendous advantage. It's the reason that